REMARKS

Entry of the foregoing, reexamination and further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested.

As is correctly reflected in the Office Action summary, Claims 1-49 are pending in the application. Claims 5-7, 30 and 44-46 have been withdrawn from consideration as allegedly drawn to nonelected species. Claims 1-4, 8-29, 31-43, and 47-49 were rejected. Acknowledgment has been made of a claim for foreign priority and certified copies of all priority documents have been received.

By the foregoing amendments, Claims 41 and 42 were amended to delete reference to prevention of cutaneous atrophy, stretch marks, alopecia, and acne. Claim 41 was further amended to delete the word "including" and the text which followed. Claim 50 has been added. Claim 50 incorporates the content of the "including" clause of former Claim 41. No new matter has been added.

A. Rejections Under 35 U.S.C. §112, First and Second Paragraphs

1. Claims 41 and 42

Turning now to the Official Action, Claims 41 and 42 were rejected under 35 U.S.C. § 112, first paragraph, as purportedly not enabled for preventing cutaneous atrophy, stretch marks, alopecia and acne. According to the Examiner, prevention of these disorders is inconsistent with what is known in the art and "prevention" indicates that the

subject *never* experiences any characteristics associated with these disorders. *See Official Action, Page 4.* These rejections are respectfully traversed.

Not to acquiesce in the Examiner's rejections, but solely to facilitate prosecution, Applicants have deleted all references to prevention in Claims 41 and 42. Applicants believe that these amendments have rendered the Examiner's rejections moot. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 112, first paragraph, rejections against Claims 41 and 42.

2. Claims 1, 3, 18, 19, 27 and 38

Next, Claims 1, 3, 18, 19, 27, and 38 were rejected under 35 U.S.C. § 112, second paragraph, as purportedly indefinite. These rejections are respectfully traversed.

Definiteness of claim language must be analyzed, not in a vacuum, but in light of the content of the application disclosure, the teachings of the prior art, and the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. *See M.P.E.P § 2171.* Using this framework, Applicants maintain that Claims 1, 3, 18, 19, 27, and 38 do not violate 35 U.S.C. § 112, second paragraph.

a. "said at least one biologically active agent (A) being non-solubilized therein in micronized particulate state"

According to the Examiner, this phrase is vague and indefinite because it is not clear what the active agent is solubilized in. Applicants respectfully disagree.

The Specification specifies that the "micronized biologically active compound is not solubilized in the compositions of the invention. By the expression 'not solubilized' is

intended a biologically active compound which is dissolved to less than 0.05% and preferably to less than 0.01% by weight relative to the weight of each of the other compounds, taken individually, of the composition." *Specification, Page 10, ¶ 0064.*

The limitation in this phrase is not what the active agent is solubilized *in*, but rather what it is *not solubilized in* — the compositions of the invention.

Applicants maintain that one of skill in the art would readily understand what is meant by "said at least one biologically active agent (A) being non-solubilized therein in micronized particulate state." Applicants respectfully request withdrawal of the 35 U.S.C. § 112, second paragraph, rejections against Claims 1, 3, 18, 19, 27, and 38.

b. "at lest 80%, numerically, of said micronized ..."

According to the Examiner, the phrase "at least 80%, numerically, of said micronized particles having diameters from 1 to 10 microns and at least 50%, also numerically, having diameters of less than 5 microns" in Claim 1 is vague, indefinite, and confusing. In particular, the Examiner notes that 80% plus 50% exceeds 100%. Applicants respectfully disagree and maintain that Claim 1 is not vague, indefinite, or confusing.

Paragraph 0011 of the Specification indicates that at least 80%, and preferably at least 90%, of the micronized biologically active compounds should have a diameter ranging from 1 to 10 microns. Paragraph 0011 of the Specification also indicates that at least 50% of the micronized biologically active compounds should have a diameter of less than 5 microns. Claim 1 contains similar parameters.

Paragraph 0011 tells one of skill in the art that the majority (*e.g.*, 80-90%) of the population of particles must fall within the 1-10 micron range; and than within that range, over half of the particles are smaller than 5 microns. Therefore, these parameters are not described as an additive percentage, but instead as a description of two characteristics of the same population. One of skill in the art would not consider this phrase to be vague, indefinite, or confusing.

Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 112, second paragraph, rejections to Claim 1 due to this phrase.

c. "major" and "minor"

According to the Examiner, these terms are relative, and therefore indefinite. Applicants respectfully disagree.

The Specification indicates that the emulsifying system comprises at least one copolymer prepared from a **major** fraction of monoolefinically unsaturated C_3-C_6 carboxylic acid monomer or anhydride thereof and a **minor** fraction of acrylic acid ester monomer containing a fatty chain. *Specification Page 4, ¶ 0014.* The Specification then states that the emulsifying copolymers are prepared by polymerizing a "predominant amount" of monoolefinically unsaturated carboxylic acid monomer or anhydride thereof, with a "smaller amount" of acrylic acid ester monomer containing a fatty chain. *Specification Page 4, ¶ 0015.* The amount of carboxylic acid monomer or anhydride thereof is listed as preferably ranging from 80% to 98% by weight, and more particularly from 90% to 98% by weight. The amount of acrylic acid ester containing a fatty chain is listed as advantageously being present in amounts of from 2% to 20% by weight, and more

particularly from 1% to 10% by weight. These percentages are calculated relative to the total weight of the two monomers. *Specification Page 4, ¶ 0015*. Using the information contained in the Specification, one of skill in the art would readily appreciate what is meant by "major" and "minor" in Claim 3.

Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 112, second paragraph, rejections to Claim 3 due to "major" and "minor."

d. "difficultly soluble" and "pH conditions which are comparable..."

According to the Examiner, these are relative terms, and therefore indefinite. Applicants respectfully disagree. The fact that claim language, including terms of degree, may not be precise, does not automatically render the claim indefinite. *Seattle Box Co. v. Industrial Crating & Packing, Inc.*, 731 F.2d 818 (Fed. Cir. 1984).

One of skill in the art is instructed by the Specification that "[a]ny biologically active agent which is insoluble or difficult to dissolve in water or in a hydrophilic medium under pH conditions which are compatible with the skin, *i.e.*, a pH of from 5 to 7, and which can be micronized, is well suited for formulation into the emulsions of the present invention." Therefore, one of skill in the art would appreciate that "difficulty soluble" indicates that the agent is difficult to dissolve in water or a hydrophilic medium under pH conditions which are compatible with the skin. From this same passage, one of skill would also appreciate that "pH conditions which are compatible with the skin" refers to a pH of from 5 to 7.

Because one of skill in the art can readily ascertain what is meant by "difficulty soluble" and "pH conditions which are compatible with the skin," Applicants respectfully

request withdrawal of the 35 U.S.C. § 112, second paragraph, rejections to Claim 18 due to these phrases.

e. "modulates"

According to the Examiner, this term is relative, and therefore indefinite. Applicants respectfully disagree.

"Modulate" means to adjust or adapt, and is an art-accepted way to describe an agent's ability to adjust or adapt its native properties. Because one of skill in the art would readily understand what is meant by "modulate," Applicants respectfully request withdrawal of the 35 U.S.C. § 112, second paragraph, rejections to Claim 19 due to this phrase.

f. "derivative"

According to the Examiner, the phrases "a fatty acid or fatty alcohol, or derivative thereof" of Claim 27 and "a cellulose derivative" of Claim 38 are vague and indefinite because the metes and bounds of these claims are unascertainable. Applicants respectfully disagree.

With respect to "a fatty acid or fatty alcohol, or derivative thereof" in Claim 27, Applicants maintain that one of skill in the art would readily appreciate the metes and bounds of Claim 27. In the chemical field, it is art-recognized that a "derivative" is a compound derived or obtained from another containing essential elements of the parent substance. Accordingly, one of skill in the art would understand what fatty acid or fatty alcohol derivatives are.

With respect to "a cellulose derivative" in Claim 38, the foregoing description of "derivative" applies. In addition, Page 14, ¶ 0082, of the Specification states that "cellulose derivatives" include "hydroxyproplymethylcellulose or hydroxyethylcellulose." Accordingly, one of skill in the art would readily understand what a cellulose derivative is.

In light of the foregoing, Applicants respectfully request withdrawal of the 35 U.S.C. § 112, second paragraph, rejections to Claims 27 and 38 due to the cited phrases.

B. Rejections Under 35 U.S.C. § 103(a)

When applying 35 U.S.C. § 103, four tenets of patent law must be adhered to: (1) the claimed invention must be considered as a whole, (2) the references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination, (3) the references must be viewed without the benefit of impermissible hindsight vision, and (4) a reasonable expectation of success is the standard with which obviousness is determined. *See MPEP § 2141*, citing *Hodosh v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143 (Fed. Cir. 1986). Moreover, to establish a *prima facie* case of obviousness, three basic criteria must be met: (1) there must be some suggestion or motivation to modify the reference or to combine reference teachings, (2) there must be a reasonable expectation of success, and (3) the prior art reference(s) must teach or suggest all of the claim limitations. *See MPEP § 2142.*

Moreover, mere identification of each claimed element in the prior art is not sufficient to negate patentability. *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998). Instead, there "must be a teaching or suggestion within the prior art, or within the general

knowledge of a person of ordinary skill in the filed of the invention, to look to particular sources of information, to select particular elements, and to combine them in the way they were combined by the inventor." *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 536 (Fed. Cir. 1998). Otherwise, sophisticated scientific fields would rarely, if ever, experience a patentable technical advance. *Rouffet*, 149 F.3d at 1357.

1. Claims 1-3, 8-10, 18-24, 26-29, 40-43, and 47-49

Claims 1-3, 8-10, 18-24, 26-29, 40-43, and 47-49 were rejected under 35 U.S.C. § 103(a) as purportedly unpatentable over European Patent No. 0 268 164 to Lockhead et al. ("Lockhead") in view of U.S. Patent No. 6,136,332 to Grollier et al. ("Grollier"). According to the Examiner, it "would have been obvious to one of ordinary skill in the art at the time the invention was made to add the nadifloxacin of Grollier to the emulsion of Lockhead because both are directed towards cosmetic compositions that impart skin care benefits." These rejections are respectfully traversed.

Applicants maintain there would be no motivation to combine the cited publications because the publications are incompatible. It is improper to combine publications where the publications teach away from their combination. *In re Grasselli,* 713 F.2d 731 (Fed. Cir. 1983). Furthermore, even if combined, the combination of publications fail to teach or suggest every element of the invention as claimed. Therefore, the rejection does not meet the requirements for a *prima facie* case of obviousness.

Lockhead relates to stable oil-in-water emulsions containing water, oil, a neutralizing agent, and a lightly crosslinked modified polymer, and to products based on such emulsions. *See Lockhead, Page 2, Lines 28-31*. The modified polymers have a

predominant amount of an acrylic acid and a smaller amount of a long chain acrylate monomer and act as a primary emulsifier. *See Lockhead, Page 2, Lines 28-31.*

Grollier relates to substantially non-aqueous, topically-applicable dermatological/pharmaceutical compositions well suited for preventatively and/or curatively therapeutically treating human skin or mucous membranes. The compositions of Grollier contain at least one volatile oil, at least one phenylated silicone oil, and at least one dermatologically and/or pharmaceutically active agent. *See Grollier, Column 2, Lines 7-11.* The compositions of Grollier create "films" that exhibit very good hold, transfer little, if at all, and migrate little, if at all. *See Grollier, Column 2, Lines 3-6.*

Applicants maintain that Lockhead and Grollier are incompatible. As indicated above, Lockhead pertains to oil-in-**water** emulsions, whereas the compositions of Grollier are substantially **non-aqueous**. *See Grollier, Claim 1.* Accordingly, these publications are inapposite and may not properly be combined.

Even assuming that these publications could be properly combined, they fail to disclose all limitations of Applicants' claimed invention. Applicants' invention pertains to oil-in-water emulsions containing at least one biologically active agent that is non-solubilized and micronized, where at least 80% of said micronized particles have diameters from 1-10 microns, and where at least 50% of said particles have diameters of less than 5 microns. Neither Lockhead nor Grollier provide these non-solubilization, micronization, and size limitations of Applicants' claimed invention. In fact, Lockhead states that "oil-in-water emulsions prepared with the modified polymer have a much larger particle size [than

conventional oil-in-water emulsions] averaging about 50 microns and are in the range of 10 to 100 microns." *Lockhead, Page 8, Lines 5-7.*

Applicants maintain that a *prima facie* case of obviousness has not been made out because there is no suggestion or motivation to the combine the cited publications. In fact, the two publications are inapposite and teach against combination. Moreover, the publications do not contain all limitations of the rejected claims. Applicants maintain that select elements from Applicants' invention have merely been identified in Lockhead and Grollier, which is insufficient to negate patentability. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejections of Claims 1-3, 8-10, 18-24, 26-29, 40-43, and 47-49 over Lockhead in view of Grollier.

2. Claims 1-4, 8-29, 31-43, and 47-49

Claims 1-4, 8-29, 31-43, and 47-49 were rejected under 35 U.S.C. § 103(a) as purportedly unpatentable over U.S. Patent 5,073,372 to Turner et al. ("Turner") in view of Lockhead in further view of Grollier, U.S. Patent No. 5,882,633 to Pisson et al. ("Pisson"), U.S. Patent No. 5,916,543 to Kaplan ("Kaplan"), U.S. Patent No. 4,486,405 to Klein ("Klein") and U.S. Patent No. 5,980,939 to Kim et al. ("Kim"). These rejections are respectfully traversed.

The deficiencies of Lockhead and Grollier are detailed above. The emulsions of Turner are of the oil-in-water type, and thus are as incompatible with Grollier as were the emulsions of Lockhead. Turner requires from about 0.01% to about 5%of a cationic surfactant. *Turner, Column 5, Lines 30-39.* Applicants claimed invention does not require such a cationic surfactant. Accordingly, there is no reason why one of skill in the art

would look to Turner for guidance. Moreover, because Applicants' claimed invention lacks an "essential component" of Turner, one of skill in the art would have no reasonable expectation of success in arriving at Applicants' claimed invention.

The compositions of Pisson contain three essential elements: an amide, a dibenzoylmethane derivative, and a 1,3,5-triazine derivative. *See Pisson, Column 2, Lines 25-35.* The compositions of Pisson are particularly photostable and are, therefore, effective sunscreens.

The compositions of Pisson require three essential elements which are not required by Applicants' compositions. Moreover, the compositions of Pisson do *not* contain a biologically active agent, whereas such an agent is essential to Applicants' compositions.

Because its essential elements are lacking therein, Pisson may not properly be combined with Lockhead, Grollier, and/or Turner. In addition, Pisson teaches away from combining these publications for the same reason — that is, their essential elements differ. Finally, due to this disparity in components, one would not reasonably have expected to succeed in arriving at Applicants' claimed compositions.

The emulsions of Kaplan contain a nonaqueous phase, an aqueous phase, an oil-in-water emulsifier, and a water-in-oil emulsifier. An advantage of the Kaplan emulsions is that they exhibit exceptionally short rub-in times. *See Kaplan, Column 1, Lines 32-41.* The emulsions of Kaplan do not contain biologically active agents, as do Applicants' compositions. In addition, Kaplan is silent as to the use of an emulsifying system comprising carboxylic acid copolymers.

The emulsions of Kaplan, like the emulsions of Turner, are incompatible with Grollier. The emulsions of Kaplan do not possess the essential elements of Lockhead, Grollier, Turner, or Pisson. Accordingly, these publications may not properly be combined. Even if combined, these publications do not contain all elements of Applicants' compositions. Because of the disparity in essential elements between the publications and the failure of these publications to teach or suggest Applicants' biologically active agents coupled with an emulsifying system, one of skill would not reasonably expect to successfully obtain Applicants' invention.

The compositions of Klein require a relatively large amount of pigment and a mixture of two alkoxylated surfactants. *See Klein, Abstract.* The compositions of Klein are aqueous, and thus incompatible with Grollier. The compositions of Klein do not contain biologically active agents, as do Applicants' compositions, nor do the compositions of Klein contain the essential elements of the other cited publications.

Based on the deficiencies, Klein may not properly be combined with Lockhead, Grollier, Turner, Pisson, and/or Kaplan. Even if combined, there would not exist all elements of Applicants' compositions nor a reasonable expectation of success in achieving Applicants' compositions which are particularly well-suited for promoting the penetration of biologically active agents to the base of hair follicles.

The compositions of Kim, intended for oral administration, contain a cyclosporin, an oil component, a hydrophilic cosurfactant, and a surfactant. *See Kim, Abstract.* These four components are "essential." *See, Kim Column 6, Lines 16-18, 27-28; Column 7,*

Lines 46-47; and Column 8, Lines 28-30. Accordingly, absence of any one of these "essential" elements runs contrary to the teachings of Kim.

Applicants' compositions, like the compositions of Lockhead, Grollier, Turner, Pisson, Kaplan and Klein, fail to contain all four Kim essential elements. This goes against combining Kim as suggested by the Examiner. Moreover, absence of and/or substitution of these four essential elements thwarts any reasonable expectation of success one would have in arriving at Applicants' compositions.

In summary, the compositions of the cited publications (Lockhead, Grollier, Turner, Pisson, Kaplan, Klein, and Kim) require competing essential elements, which makes their combination impermissible. The compositions of the cited publications are directed to different fields than Applicants' compositions — from photostable sunscreens to oral immunosuppressants. Accordingly, one would not look to these seven publications for guidance. If, somehow, one *did* look to these seven publications, he would not have been motivated to modify them as suggested by the Examiner. The Examiner has merely identified elements of Applicants' invention in these publications. This is not sufficient to negate patentability. Even if somehow motivated to combine these publications as suggested, there would be no reasonable expectation of success and such a combination would lack all limitation of Claims 1-4, 8-29, 31-43, and 47-49.

Based on the foregoing, Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejections against Claims 1-4, 8-9, 31-43, and 47-49 over Lockhead, Grollier, Turner, Pisson, Kaplan, Klein, and Kim.

3. Claims 1-4, 8-29, 31-43, and 47-49

Claims 1-4, 8-29, 31-43, and 47-49 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over U.S. Patent No. 5,750,122 to Evans et al. ("Evans") in view of Lockhead in further view of Grollier, Pisson, Klein, and Kim. These rejections are respectfully traversed.

The deficiencies of Lockhead, Grollier, Pisson, Klein, and Kim are discussed above. Evans does not cure these deficiencies.

Evans pertains to compositions useful for treating hair or skin, and contain panthenol and at least one polyalkylene glycol. *See Evans, Column 2, Lines 19-36.* The compositions of Lockhead, Grollier, Pisson, Klein, and Kim do not require panthenol and polyalkylene glycol — making the combination of these publications impermissible. Due to the varied nature of these cited publications, one would not look to the collection of publications relied upon by the Examiner. Moreover, even if combined, this combination would not reasonably be expected to succeed nor would it contain all elements of Applicants' compositions.

Based on the foregoing, Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejections of Claims 1-4, 8-29, 31-43, and 47-49 over Evans in view of Lockhead, Grollier, Pisson, Klein, and Kim.

4. Claims 1-4, 8-29, 31-43, and 47-49

Claims 1-4, 8-29, 31-43, and 47-49 were rejected under 35 U.S.C. § 103(a) as purportedly unpatentable over Pisson in view of Lockhead in further view of Grollier, Kaplan, Klein, and Kim. These rejections are respectfully traversed.

The deficiencies of Pisson, Lockhead, Grollier, Kaplan, Klein, and Kim are detailed above. Notably, the compositions of Pisson contain three essential elements which are lacking in the cited publications, making impermissible such a combination. Moreover, the fields of these publications are varied, and thus one of skill in the art would not call upon them for guidance. Finally, Applicants' invention may not be used as a template for assembling an invention. Applicants maintain that the Examiner has not made out, and cannot make out, a *prima facie* case of obviousness. Instead, of select elements of Applicants' invention have merely been identified in the cited publications. This is insufficient to negate patentability.

Based on the foregoing, Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejections against Claims 1-4, 8-29, 31-43, and 47-49 over Pisson in view of Lockhead, Grollier, Kaplan, Klein, and Kim.

CONCLUSION

From the foregoing, further and favorable consideration in the form of a Notice of Allowance is respectfully requested and earnestly solicited.

In the event that there are any questions relating to this response, or the application in general, it would be greatly appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,

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Date: September 18, 2002

Attachment to the Amendment and Reply Dated September 18, 2002
Marked-up Claims 41 and 42

41. A regime or regimen:

(1) for treating dermatological conditions/afflictions associated with a keratinization disorder related to differentiation and proliferation, [including common acne, comedones, polymorphonuclear leukocytes, rosacea, nodulocystic acne, acne conglobata, senile acne and secondary acne, including solar, medication-related or occupational acne,] or

(2) for treating another keratinization disorder, [including ichtyosis, an ichtyosiform state, Darier's disease, palmoplantar keratoderma, leukoplasia, a leukoplasiform state, and cutaneous or mucous (buccal) lichen,] or

(3) for treating another dermatological condition/affliction associated with a keratinization disorder manifesting an inflammatory and/or immunoallergenic component, [including all forms of psoriasis, whether cutaneous, mucous or ungual psoriasis, psoriatic rheumatism, cutaneous atopy, eczema, respiratory atopy, gingival hypertrophy,] or for treating inflammatory conditions which manifest no keratinization disorder, [including rosacea,] or

(4) for treating all dermal or epidermal proliferations, whether benign or malignant and whether of viral or non-viral origin, [including common warts, flat warts, verruciform epidermodysplasia, oral or florid papillomatoses and proliferations induced by ultraviolet radiation, basocellular or spinocellular epithelioma,] or

(5) for treating bullosis or a collagen disease state, or

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Marked-up Claims 41 and 42

(6) for repairing or combating aging of the skin, whether photoinduced or chronological aging, or for reducing pigmentations and actinic keratosis, or any pathology associated with chronological or actinic aging, or

(7) for [preventing or] curing the stigmata of epidermal and/or dermal atrophy induced by local or systemic corticosteroids, or other form of cutaneous atrophy, or

(8) for the [preventive or] curative treatment of cicatrization disorders, for [preventing or] repairing stretch marks, or for promoting cicatrization, or

(9) for combating disorders of sebaceous functioning, [including acneic hyperseborrhoea or simple seborrhoea,] or

(10) for the [preventive or] curative treatment of cancerous or precancerous disease states, or

(11) for the treatment of inflammatory conditions/afflictions, [including arthritis,] or

(12) for the treatment of any skin condition/affliction of viral origin, or

(13) for the [preventive or] curative treatment of alopecia, or

(14) for the treatment of dermatological conditions/afflictions manifesting an immunological component, or

(15) for the treatment of skin disorders caused by exposure to UV radiation, or

(16) for the treatment of dermatological conditions/afflictions associated with inflammation or infection of the tissues surrounding the hair follicles, [including

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Marked-up Claims 41 and 42

colonization or microbial infection, impetigo, seborrhoeic dermatitis, folliculitis, sycosis barbae,] or

(17) for accelerating or promoting hair loss, comprising topically applying onto the skin, scalp and/or hair of a candidate subject in need of such treatment, for such period of time as required to elicit the desired biological response, a topically applicable cosmetic/pharmaceutical oil-in-water emulsion including a discontinuous fatty phase dispersed in a continuous aqueous phase and comprising an effective amount of at least one thus-biologically active agent (A) and an effective amount of an emulsifying system (B) therefor, said at least one biologically active agent (A) being non-solubilized therein in micronized particulate state, at least 80%, numerically, of said micronized particles having diameters ranging from 1 to 10 μm and at least 50%, also numerically, having diameters of less than 5 μm.

42. The regime/regimen as defined by Claim 41, comprising [preventively or] curatively treating acne.